



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

gslfyd

Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3145

February 7, 2005

Ref: 2005-DAL-WL-12

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURNED RECEIPT REQUESTED**

Mr. Dwayne Woody, Owner  
W.W. Cattle Company  
6391 Old Agnes Road  
Poolville, TX 76487

Dear Mr. Woody:

An inspection of your feed manufacturing operation located at 6391 Old Agnes Road, Poolville, Texas, was conducted on August 27 and September 2, 2004 by an Investigator from the Food and Drug Administration (FDA). The inspection found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed (21 CFR 589.2000). This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Because you failed to follow the requirements of this regulation, the corn dogs containing cooked meat and other ingredients used for manufacturing ruminant feed are adulterated within the meaning of Section 402(a)(2)(C)(i) and misbranded within the meaning of Section 403(a)(1) of the Federal, Food, Drug and Cosmetic Act (the Act).

The use of protein derived from mammalian tissues, as defined in 21 CFR 589.2000(a)(1), as an animal feed ingredient or in animal feeds must comply with the requirements of 21 CFR 589.2000. That regulation provides that the use of protein derived from mammalian tissues in ruminant feed is prohibited. The definition of "protein derived from mammalian tissues" excludes inspected meat products which have been cooked and offered for human food, such as the corn dogs you receive, that have been further heat processed for use in animal feed. This requirement was previously communicated to you in an April 3, 2001 letter from the Texas State Feed and Fertilizer Control Service. In the absence of the required further heat processing, such products for use in ruminant feeds are adulterated under Section 402(a)(2)(C)(i) of the Act.

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W.W. Cattle Company  
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Our inspection revealed that whole corn dogs which contain protein derived from mammalian tissues and are sold by your firm to the [REDACTED] for use in ruminant feed are not subjected to further heat processing, causing them to be adulterated feed under Section 402(a)(2)(C)(i) of the Act.

In addition, because the whole corn dogs are not subjected to further heat processing and are thus not exempt from the regulation, they must bear the caution statement, "Do not feed to cattle or other ruminants." Our inspection revealed that they do not bear this caution statement, which causes them to be misbranded animal feed under Section 403(a)(1) of the Act.

Copies of the BSE Guidance documents 69, 70 and 76 were provided to Mr. Billy J. Brooks, General Manager, and further discussed by personnel from the Texas Feed and Fertilizer Control Service. Also, you received a copy of the 21 CFR 589.2000, the BSE regulation which was again explained in more specific detail. These serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or a court injunction against further sale of protein derived from mammalian tissues for use in ruminant feed or ruminant feed containing such materials.

It is necessary for you to take action on this matter now. Please notify this office in writing within fifteen (15) working days from the date you received this letter. Your response should specifically identify the actions you are taking to correct the violations that would involve the continued use of corn dogs to manufacture ruminant feed and provide specific timeframes for achieving compliance. Your reply should be sent to Edwin Ramos, Compliance Officer, at the above stated address. If you have any questions concerning the stated matters, you may contact Mr. Ramos at 214-253-5218.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael A. Chappell", with a stylized, flowing script.

Michael A. Chappell  
Dallas District Director

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